DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse <u>History Form – FORM FDA 3472</u>

Form approved: OMB No. 0910-0417 Expiration Date: May 31, 2000 See OMB Statement on reverse

Please complete this form to detail any relevant historical information that relates to your corporate name and/or products to other names, and return as indicated on the instruction page. This can include industry acronyms, divisions, subsidiaries, buyouts, mergers, and parent-child relationships. For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information			
1.	Manufacturer Name			
2.	Division			
	(see instructions on the back of this form)			
3.	Enter Your FDA Assigned			
	Owner/Operator Number History Detailed Information			
	History Detailed Information			
4.	Name	5.		Relationship
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DUPLICATE THIS FORM AS NECESSARY

Federal Y2K Biomedical Equipment Clearinghouse

Instructions - FORM FDA 3472

This form has been filled-in with the information your company has provided, if applicable. Please verify and correct, or provide any missing information and return as indicated on the instruction page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday, Eastern Time or Email the Y2K Clearinghouse at v2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information				
Manufacturer Name	Name of the Manufacturer submitting the product information.			
2. Division	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.			
Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K compliance information is FDA regulated, please enter your FDA assigned Owner/Operator Number.			
History Information				
4. Name	Historical name associated with the manufacturer name specified in Line #1.			
5. Relationship	Description of how the historical name (Line #4) is related to the manufacturer name specified in Line #1. Place the appropriate number related to the relationship reason in the space provided. See Relationship Definitions below.			
6. Comments	Additional detail information that may be relevant in explaining the corporate history relationship between the historical name (Line #4) and the manufacturer name (Line #1)			

Relationship Definitions

Definition of Terms:

- 1. The "Reporting Manufacturer" is the manufacturer name referred to in Line #1.
- 2. The "Identified Manufacturer" is the historical name(s) referred to in Line #4.

#	Relationship Reason	Definition
1.	Acronym/Abbreviation	Well-known or common alphabetical or numeric characters that serve as a
		recognizable alternative for the manufacturer name.
2.	Distributor for Manufacturer	An independent company which distributes products for the reporting manufacturer and
		does not manufacture biomedical equipment of its own.
3.	Division	A subset of a manufacturer which may or may not operate independently and may or
		may not report the same Y2K compliance status.
4.	Former Name of Manufacturer	The identified name is a prior name of the reporting manufacturer. This may be due to
		a sell, merger, or just a name change.
5.	Former Name Prior to Merger	A former name of one of the companies involved in a merger.
6.	Former Parent	The identified manufacturer formerly owned the reporting manufacturer.
7.	Former Subsidiary or Division of Manufacturer; Sold	A division or subsidiary that was sold to another company. When available, the
	to (See Comments)	purchasing company will be listed in the history comments.
8.	Manufacturer Purchased Company	The reporting manufacturer purchased the identified manufacturer.
9.	Manufacturer Purchased Partial Product Line/Old Company Still Exists (See Comments)	The reporting manufacturer purchased one or more products from the identified manufacturer; this company still manufactures products. The reporting manufacturer is only submitting the Y2K compliance status for the identified manufacturer product lines listed in the history comments. The identified manufacturer's Y2K status may or may not be available in the status database.
10.	Manufacturer Purchased Partial Product Line/Old Company Does Not Exist (See Comments)	The reporting manufacturer purchased one or more products from the identified manufacturer; this company no longer manufactures products. The reporting manufacturer is only submitting Y2K compliance status information for the identified manufacturer product lines listed in the history comments. The status of the identified manufacturer's remaining products may or may not be known.
11.	Parent	The identified manufacturer owns the reporting manufacturer.
12.	See Comments	The comment section is used in cases where either the relationship is not identified
		within the 14 categories or where a relationship needs further explanation.
13.	Sister Company	The same company as the reporting manufacturer owns the identified company. Their
		Y2K compliance status may or may not be the same.
14.	Subsidiary	The reporting manufacturer owns the identified manufacturer; however, the reporting
		manufacturer's compliance status may or may not apply to the identified manufacturer.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K) Center for Devices and Radiological Health, FDA 9200 Corporate Boulevard Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.